K024345

FEB 2 6 2003

510(k) SUMMARY

Submitted by:	Barnes, Richardson & Colburn 1225 Eye Street, N.W. Washington, D.C. 20005
Contact:	Stephen Brophy Tel: (202) 457-0300
Date Prepared:	December 16, 2002
Subject Device:	B-07 Stairway Chairlift
Predicate Device:	.Bruno Electra-Ride (510(k) number K921648)
Subject Product Description:	The B.07 is a stairway chairlift designed to carry a rated load of 300 lb. directly up and down a set of stairs in a residence or public setting. The B.07 is designed to travel a maximum 32 feet at a rated speed of 18 feet per minute. Safety switches installed on the B.07 stop the carriage when it reaches the top or bottom of the stairway. The footrest incorporates obstruction sensors, which will stop the carriage if an obstacle is encountered on the stairs. The B.07's simple design allows for easy operation, quick installation and reliability. Its rail is made of extruded aluminum and hides the drive components and the traveling cable. It is a vertical mount rail that attaches to the tread so wear marks cannot develop on its outer surface due to the internal rolling system. The angle is fully adjustable for staircases of 25 to 45 degrees. The seat and footrest height are adjustable for both short and tall people. The chair can be swiveled at the top and bottom landing for easy and safe access to the seat. The stairlift can be transformed from a left hand to a right hand side on the site of installation within minutes. The device uses a roller chain drive system with an aluminum rail that allows for modifying the length of travel without having a weld. For safety, the B.07 is equipped with a safety brake, an obstruction sensor, a swiveled seat detector and a final limit switch. The chair lift can also be folded in the up position as to facilitate access to the staircase.
Intended Use:	The product will be used by the patient to assist in navigating a specific set of stairs. This is a self-contained product that is mounted to the tread of a staircase. A trained dealer will install the unit, test it and teach the end user how to operate it. The typical user is someone who has limited function of their knees, hips or ankles and/or has trouble bending these joints. Other users include rehabilitated stroke victims, those inflicted with MS, arthritis, heart disease, and those who cannot handle the exertion of

walking up and down the stairs. The unit may be recommended by doctors or physical therapists, for those who are recuperating but a large number of users acquire a stairway elevator just because to eases the burden of climbing stairs, improving their quality of life. For those who are wheelchair bound, it requires that they be able to transfer and is usually an option only if the physical limitations of the residence prohibits a vertical elevator.

Product Comparison:

The B.07 is substantially equivalent to the Bruno Electra-Ride (K9721648). Both products are used by the patient to assist in navigating a specific set of stairs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Services Industriels Savaria, Inc.
c/o Mr. Stephen W. Brophy
Barnes, Richardson & Colburn
1225 Eye Street, N.W., Suite 1150
Washington, DC 20005

Re: K024345
Trade/Device Name: B.07 Stairway Chairlift
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: II
Product Code: ILK
Dated: February 5, 2003
Received: February 5, 2003

Dear Mr. Brophy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) :

DEVICE NAME : B.07 Stairway Chairlift

INDICATIONS FOR USE:

The product will be used by the patient to assist in navigating a specific set of stairs. This is a self-contained product that is mounted to the tread of a staircase. A trained dealer will install the unit, test it and teach the end user how to operate it. The typical user is someone who has limited function of their knees, hips or ankles and/or has trouble bending these joints. Other users include rehabilitated stroke victims, those inflicted with MS, arthritis, heart disease, and those who cannot handle the exertion of walking up and down stairs. The unit may be recommended by doctors or physical therapists, for those who are recuperating but a large number of users acquire a stairway elevator just because it eases the burden of climbing stairs, improving their quality of life. For those who are wheelchair bound, it requires that they be able to transfer and is usually an option only if the physical limitations of the residence prohibits a vertical elevator.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter-Use /
(Per 21 CFR 801.109 (Optional Format 1)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024345